

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bruno DE LIGNIERES

Title: TREATMENT OF MASTALGIA WITH
4-HYDROXY TAMOXIFEN

Appl. No.: 10/734,640

Filing Date: 12/15/2003

Examiner: U. Ramachandran

Art Unit: 1617

Confirmation Number:

9061

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

A copy of each newly cited non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

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TIMING OF THE DISCLOSURE

The listed documents are submitted before the mailing date of a final Office Action.

RELEVANCE OF EACH DOCUMENT

Applicant's understanding of the relevance of the previously submitted foreign language documents is provided below.

Barrat et al. (1990) describes the percutaneous administration of placebo, estradiol or progesterone gels to patients with various benign breast diseases, and reports that progesterone administered percutaneously to the breast does not increase mitotic activity, but instead decreases it.

Kutten et al. (1985) has an English abstract which reflects its relevance. For example, the reference reports that percutaneously administered 4-OHT was more concentrated in tumor tissue and estradiol receptor rich subcellular fractions than in non-cancerous tissue, and that 4OHT was retained in breast tissue to a greater extent than tamoxifen.

Mauvais-Jarvis et al. (1991) provides a short review on the hormonal treatment of benign "mastopathies." The reference note two methods of action of hormonal treatment: stopping the production of gonadotrophins ("chemical castration") and preventing hormones from binding to their nuclear receptors using antiestrogens. With regard to the latter approach, the reference comments on the drawbacks of oral tamoxifen therapy. The reference notes that percutaneous 4-OHT has been shown to penetrate the skin and hypothesizes that it could prove useful in antiestrogen therapy. While not directly equivalent to this reference, two additional (English-language) articles submitted herewith address similar topics. (Mauvais-Jarvis, "Mastodynia and fibrocystic disease." Curr. Ther. Endocrinol. Metab. 3: 280-284 (1988); Mauvais-Jarvis &, Sitruk-Ware, "Hormonal therapy of benign breast disease." Senologie et Pathologie Mammaire. 4ème Congrès International, Paris 1-4 Sep 1986: 128-132.)

Applicant also submits copies of Office Actions cited in co-pending applications 10/734,638 and 10/734,644.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The required fee is submitted herewith. The Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 12, 2007

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: June 12, 2007

(use as many sheets as necessary)

Complete if Known

Application Number	10/734,640
Filing Date	12/15/2003
First Named Inventor	Bruno DE LIGNIERES
Art Unit	1617
Examiner Name	U. Ramachandran

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PTO/SB/08

Sheet 1 of 1 Attorney Docket Number 029488-0111

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	G1	J. BARRAT et al., "Effet <i>in vivo</i> de l'administration locale de progestérone sur l'activité mitotique des galactophores humains", J. Gynecol. Obstet. Biol. Reprod. 19: 269-274 1990.	
	G2	Frédérique KUTTENN et al., "MÉDECINE ET THÉRAPEUTIQUE", C.R. Acad. Sc. Paris, , Série III, No. 12, 1985, 300:457-461.	
	G3	P MAUVAIS-JARVIS, "Le traitement hormonal des mastopathies benignes", Bull Cancer (1991) 78, 365-371.	
	G4	Mauvais-Jarvis, "Mastodynia and Fibrocystic Disease," Current Therapy in Endocrinology and Metabolism, 3:280-284 (1988).	
	G5	P. Mauvais-Jarvis, "Hormonal Therapy of Benign Breast Disease," Senologie et Pathologie Mammaire. 4ème Congrès International, Paris 1-4 September 1986, pp. 128-132.	
	G6	10/734,638 May 5, 2006 Office Action (22 pgs.)	
	G7	10/734,638 October 2, 2006 Final Office Action (15 pgs.)	
	G8	10/734,638 January 16, 2007 Advisory Action (4 pgs.)	
	G9	10/734,638 March 13, 2007 Final Office Action (21 pgs.)	
	G10	10/734,644 August 23, 2005 Office Action (10 pgs.)	
	G11	10/734,644 February 24, 2006 Final Office Action (10 pgs.)	
	G12	10/734,644 July 7, 2006 Advisory Action (7 pgs.)	
	G13	10/734,644 April 10, 2007 Final Office Action (11 pgs.)	

Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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